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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,654

04/19/2004

James Nadeau

020187.0208PTUS

2135

44640

7590

09/28/2006

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,654

Applicant(s)

NADEAU ET AL.

Examiner

Frank W. Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-114 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-30 and 74-78, drawn to a method of detecting an analyte, classified in class 435 subclass 91.2.
 - II. Claims 31-50, drawn to a method of detecting an analyte, classified in class 435, subclass 91.2.
 - III. Claims 51-61, drawn to a method of detecting an analyte, classified in class 435, subclass 91.2.
 - IV. Claims 62-69, drawn to a method of detecting an analyte, classified in class 435, subclass 91.2.
 - V. Claims 70-73, drawn to a method of detecting an analyte, classified in class 435, subclass 91.2.
 - VI. Claims 79-82, drawn to a method of detecting an analyte, classified in class 435, subclass 91.2.
 - VII. Claims 83-112, drawn to a kit, classified in class 536, subclass 23.1.
 - VIII. Claim 113, drawn to a kit, classified in class 536, subclass 23.1.
 - IX. Claim 114, drawn to a method of quantifying a non-nucleic acid analyte, classified in class 435, subclass 91.2.
2. The inventions are distinct, each from the other because of the following reasons:

Group I and Groups II to VI and IX are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct

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searches will have to be performed. For example, the search required for Group I such as (d) of claim 1 is not required for Groups II to VI and IX while the search required for Group II such as (d) of claim 31 or the search required for Group III such as (ii) of claim 51 or the search required for Group IV such as (ii) of claim 62 or the search required for Group V such as step (iv) of claim 70 or the search required for Group VI such as (b) and (c) of claim 79 or the search required for Group IX such as step (v) of claim 114 is not required for Group I.

Group I and Groups VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in claim VI.

Group II and Groups III to VI and IX are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as (d) of claim 31 is not required for Groups III to VI and IX while the search required for Group III such as (ii) of claim 51 or the search required for Group IV such as (ii) of claim 62 or the search required for Group V such as step (iv) of claim 70 or the search required for Group VI such as (b) and (c) of claim 79 or the search required for Group IX such as step (v) of claim 114 is not required for Group II.

Group II and Groups VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

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process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in claim VI.

Group III and Groups IV to VI and IX are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group III such as (ii) of claim 51 is not required for Groups IV to VI and IX while the search required for Group IV such as (ii) of claim 62 or the search required for Group V such as step (iv) of claim 70 or the search required for Group VI such as (b) and (c) of claim 79 or the search required for Group IX such as step (v) of claim 114 is not required for Group III.

Group III and Groups VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in claim VI.

Group IV and Groups V, VI, and IX are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group IV such as (ii) of claim 62 is not required for Groups V, VI, and IX while the search required for Group V such as

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step (iv) of claim 70 or the search required for Group VI such as (b) and (c) of claim 79 or the search required for Group IX such as step (v) of claim 114 is not required for Group IV.

Group IV and Groups VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in claim VI.

Group V and Groups VI and IX are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group V such as step (iv) of claim 70 is not required for Groups VI and IX while the search required for Group VI such as (b) and (c) of claim 79 or the search required for Group IX such as step (v) of claim 114 is not required for Group V.

Group V and Groups VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in claim VI.

Groups VI and IX are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will

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have to be performed. For example, the search required for Group VI such as (b) and (c) of claim 79 is not required for Group IX while the search required for Group IX such as step (v) of claim 114 is not required for Group VI.

Group VI and Groups VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in claim I.

Groups VII and VIII are distinct and independent inventions in that they are directed to different products. As a result, different and distinct searches will have to be performed. For example, the search required for Group VII such as (b) and (c) of claim 108 is not required for Group VIII while the search required for Group VIII such as a first antigen and a second antigen of claim 113 is not required for Group VII.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Group I contains claims directed to the following patentably distinct species:

(1) the hybridization blocker oligonucleotide forms a hybrid comprising all of the bases of the first portion of the first oligonucleotide moiety (claim 6)

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(2) the hybridization blocker oligonucleotide forms a hybrid comprising less than all of the bases of the first portion of the first oligonucleotide moiety (claim 9)

The species are independent or distinct because these species are directed to different hybrids.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 1-5, 7, 8, 10-30 and 74-78.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. Group I further contains claims directed to the following patentably distinct species:

(3) the hybridization blocker oligonucleotide is combined before the deblocker oligonucleotide (claim 15)

(4) the hybridization blocker oligonucleotide is combined after the deblocker oligonucleotide (claim 16)

(5) the hybridization blocker oligonucleotide is combined simultaneously with the deblocker oligonucleotide (claim 17)

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(6) the hybridization blocker oligonucleotide is combined before the analyte and first and second proximity members (claim 18)

(7) the hybridization blocker oligonucleotide is combined after the analyte and first and second proximity members (claim 19)

The species are independent or distinct because these species are directed to different methods.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 1-14, 20-30, and 74-78.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). wherein the hybridization blocker oligonucleotide is combined

5. Group II contains claims directed to the following patentably distinct species:

(8) the releasing comprises extending a double-stranded portion of the capture oligonucleotide to displace the first oligonucleotide moiety from the hybrid between the capture oligonucleotide and the first oligonucleotide moiety (claim 44)

(9) the releasing comprises extending a double-stranded portion of the first oligonucleotide moiety to displace the capture oligonucleotide from the hybrid between the capture oligonucleotide and the first oligonucleotide moiety (claim 46)

The species are independent or distinct because these species are directed to different releasing methods.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 31-43, 45, and 47-50.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Group VII contains claims directed to the following patentably distinct species:

(10) the hybridization blocker oligonucleotide forms a hybrid comprising all of the bases of the first portion of the first oligonucleotide moiety (claim 88)

(11) the hybridization blocker oligonucleotide forms a hybrid comprising less than all of the bases of the first portion of the first oligonucleotide moiety (claim 89)

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The species are independent or distinct because these species are directed to different hybrids.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 83-87 and 90-112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Group VII further contains claims directed to the following patentably distinct species:

(12) the first and second portions of the first oligonucleotide comprise no overlapping bases (claim 97)

(13) the first and second portions of the first oligonucleotide comprise contiguous bases in common (claim 98)

(14) the first and second portions of the first oligonucleotide are the same base sequence (claim 99)

The species are independent or distinct because these species are directed to different first oligonucleotides.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 83-96 and 100-112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

September 21, 2006


FRANK LU
PRIMARY EXAMINER